Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of propolis and placebo in controlling the frequency of relapses in patients with recurrent aphthous stomatitis

Protocol summary

Summary

The purpose of this pilot study was to evaluate the potential of bee propolis in reducing the number of outbreaks of aphthous ulcers in patients with high recurrences. Participants in this trial was patients with confirmed clinical diagnosis of minor aphthous ulcers and they had at least once a month aphthous ulcer episode and a minimum interval of 2 weeks from previous treatment and drug use . patients with anaemia (based on their CBC (H1) and the hematologist consultation, blood disorders, lack of satisfaction to take part in research, Pregnancy, being under 8 years old and disabled, usage of drugs that may affect the immune system and history of previous allergy to propolis or other bees` products didn't participate in this research. In this randomized, triple blind study, 22 patients (12 case and 10 control) with minor aphthous stomatitis, referred to Oral Medicine Department of Mashad Faculty Of Dentistry from September 2011 until january2012were participated. Patients were assigned to take 500 mg of propolis or a placebo tablet daily. Subjects were examined every 2 weeks for at least 6 months. They reported a baseline ulcer frequency and were assessed biweekly for recurrence of ulcers, ulcer size, pain and burning. Results were recorded to determine if subjects had a decrease in outbreak frequency.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072214101N1**
Registration date: **2013-10-15, 1392/07/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-10-15, 1392/07/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Oral and Maxillofacial Diseases Research Center of Mashahd University of Medical Sciences

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2012-01-01, 1390/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of propolis and placebo in controlling the frequency of relapses in patients with recurrent aphthous stomatitis

Public title

The effect of bee propolis in reducing the aphthous ulcers

Purpose

Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 1 - confirmed the clinical diagnosis of minor aphthous ulcers. 2 - At least once a month aphthous ulcer recurrence . 3 - a minimum interval of 2 weeks of previous treatment 4 - spontaneous healing wounds less than 2-1 weeks. Exclusion criteria: 1 - Patients with anemia (based on the trial CBC (H1) and the hematologist), blood disorders. 2 - Lack of patient's satisfaction. 3 - Patients who are pregnant, lactating, under 8 years old and disabled. 4–usage of drugs that may affect the immune system. 5- allergy to propolis.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **22**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad Faculty of Dentistry
Street address
Mashad Faculty of dentistry, opposite Mellat park, Azadi square
City
Mashhad
Postal code
Approval date
2011-08-06, 1390/05/15
Ethics committee reference number
900097

Health conditions studied

1

Description of health condition studied
Recurrent Aphthous Stomatitis
ICD-10 code
k00-k14
ICD-10 code description
k12.0

Primary outcomes

1

Description
the frequency of recurrent aphthous stomatitis
Timepoint
monthly
Method of measurement
mean number of recurrence during a month

Secondary outcomes

1

Description
mean size of ulcers
Timepoint
Biweekly
Method of measurement
By caliper

2

Description
pain of ulcers
Timepoint
Biweekly
Method of measurement
VAS system

3

Description
time of healing
Timepoint
Biweekly
Method of measurement
mean number of days of healing of ulcers

Intervention groups

1

Description
case group of patients took a daily 500mg tablet of Propolis for 6 months
Category
Treatment - Drugs

2

Description
control group of patients took one tablet of placebo a day which have same shape as propolis tablet but without the propolis for 6 months.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad Faculty of Dentistry
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oral and Maxillofacial Diseases Research Center of Mashhad University of Medical Sciences
Full name of responsible person
Zahra Delavarian
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Mashhad Faculty of Dentistry, Opposite of Mellat Park, Azadi square
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oral and Maxillofacial Diseases Research Center of Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashad Faculty of Dentistry
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Zahra Delavarian
Position
Associated Professor of Oral Medicine
Other areas of specialty/work
Street address

Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty